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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/812,351 | 03/29/2004 | Gary Durack | INGURAN-PULSE | 2698 |
| 33549 | 7590 | 11/10/2008 | | |
| SANTANGELO LAW OFFICES, P.C. 125 SOUTH HOWES, THIRD FLOOR FORT COLLINS, CO 80521 | | | EXAMINER | |
| | | | WALLENHORST, MAUREEN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1797 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 11/10/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

BarbH@idea-asset.com
CherylS@idea-asset.com
SantangeloLawOfficesPTOnotices@yahoo.com

| | | | |
|------------------------------|---|--------------------------------------|--|
| Office Action Summary | Application No. 10/812,351 | Applicant(s) DURACK ET AL. | |
| | Examiner Maureen M. Wallenhorst | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45,47-49,51-64 and 81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45,47-49,51-64 and 81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/20/08, 10/21/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 20, 2008 has been entered.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 45, 47-49, 51-64 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Potts et al (US 2003/0078703, submitted in the Information Disclosure Statement filed on December 17, 2007) in view of Shapiro et al (article from Cytometry, vol. 4, 1983, pages 11-19, submitted in the IDS filed December 17, 2007).

Potts et al teach of a multi-channel cytometry analysis system that comprises a plurality of cytometry instruments 14a-14n adapted to operate in parallel. Any number of cytometry

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instruments 14 can be included in the system, and all are connected to an integrated platform comprising a common processor in the form of a database server 12. The database server 12 is in communication with a database 16. See Figure 1 in Potts et al. Potts et al teach that each of the cytometry instruments 14 can be a conventional apparatus such as a flow cytometer, a fluorescence-activated cell sorter or a laser scanning cytometer. Raw data collected by the cytometry instruments 14 such as detected scattered light and fluorescence is received by the common processor or database server 12 substantially continuously, and the server 12 processes the output signals from the instruments 14. For example, the light intensity values measured for a single cellular event in each of the cytometry instruments 14 is transferred to the integrated platform of the database server 12, along with experimental data concerning operating parameters of the cytometry instruments. The database server 12 performs computations with the light intensity values and the experimental data. See Figure 1 and paragraphs 0021-0022, 0025 and 0026 of Potts et al. Potts et al fail to teach that the integrated platform containing the multiple flow cytometry units 14 has a common source of electromagnetic radiation that serves to provide a light radiation beam to each cytometry unit.

Shapiro et al teach of a multistation, multiparameter flow cytometer for analyzing and sorting mixed cell populations. In one embodiment, Shapiro et al teach of the use of a single beam from an ion laser as a source for illuminating several flow cytometers. A beam splitter is used to produce two or more beams from an incoming beam, and the split beams are used to illuminate stained cells in more than one flow cytometer. Shapiro et al teach that the flow chambers of the cytometers can be of the droplet-generation type. In addition, Shapiro et al teach that electronics for multiparameter signal processing such as computers can be used to

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evaluate the data measured on each of the cytometers. See the abstract, and pages 16 and 19 in Shapiro et al.

Based upon the combination of Potts et al and Shapiro et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use a common source of electromagnetic radiation for providing an illumination light beam to each of the multiple flow cytometry units taught in the apparatus of Potts et al. since Shapiro et al teach that the provision of a common source of electromagnetic radiation to several flow cytometers is known and provides the advantage of using only a single source of light energy to illuminate multiple flow streams of particles, thus allowing multiple flow cytometers to be operated in parallel with less output of energy and less instrumentation. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. With regards to instant claim 48, it would have been obvious to one of ordinary skill in the art to analyze sperm cells with the apparatus containing multiple flow cytometry units taught by Potts et al since it is well known in the prior art to analyze and sort sperm cells with a flow cytometer. With regards to claim 54, it would have been obvious to one of ordinary skill in the art to use flow cytometry units in the apparatus taught by Potts et al that contain an epi-illumination optics system since Potts et al teach that the cytometry units can be any type of conventional cytometry apparatus, and epi-illumination optics systems are routinely used in known, commercially available flow cytometers. With regards to claims 60-61, it would have been obvious to one of ordinary skill in the art to use jet-in-air droplet flow cytometry units in the apparatus taught by Potts et al since

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Potts et al teach that the cytometry units can be any type of conventional cytometry apparatus such as fluorescence-activated cell sorters, and these are routinely jet-in-air droplet flow cytometers.

With regards to claims 53, 56-58, 62, 64 and 81, Potts et al also fail to teach that the plurality of cytometry instruments are interchangeable modules in the common housing of the analysis system, and fail to teach that the processor or database server 12 is operable to output the rate at which particles are separated in the cytometry instruments, the decision boundary used by each instrument to discriminate between particles, and the operation of one instrument in relation to another instrument. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to render each of the cytometry instruments taught by Potts et al as an interchangeable module in the common housing of the analysis system so as to allow one of the instruments to be replaced when it is not working properly without having to replace or shut down the entire analysis system, thus allowing a more efficient operation of the system. It also would have been obvious to one of ordinary skill in the art to operate the processor or database server 12 taught by Potts et al to output the rate at which particles are separated in each cytometry instrument, the decision boundary used by each instrument to discriminate between particles, and the operation of one instrument in relation to another unit since these are common control parameters in a flow cytometer controlled by a processor such as a database server that provide an indication to an operator of the cytometer as to whether it is operating properly to sort particles and the criteria used to sort the particles.

5. The references cited by applicant in the IDS filed on October 20, 2008 and October 21, 2008 and listed on the numerous 1449's have been made of record. While the statement filed

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clearly does not comply with the guidelines set forth in MPEP 2004 regarding both the number of references cited and the elimination of clearly irrelevant art and marginally cumulative information, compliance with these guidelines is not mandatory. Furthermore, 37 CFR 1.97 and 1.98 do not require that the information be material, rather they allow for submission of information regardless of its pertinence to the claimed invention. Also, there is no requirement to explain the materiality of the submitted references, however, the cloaking of a clearly relevant reference by inclusion in a long list of citations may not comply with Applicant's duty of disclosure. See *Penn Yan Boats, Inc. v. Sea Lark Boats Inc.*, 359 F. Supp. 948, aff'd 479 F.2d 1338." There is no duty for the Examiner to consider these references to a greater extent than those ordinarily looked at during a regular search by the Examiner. Accordingly, the Examiner has considered these references in the same manner as references encountered during a normal search of Office search files.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1797

mmw

November 5, 2008

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1797